COMBINED PERCUTANEOUS CARDIOPULMONARY BYPASS (PBY) AND INTRA-AORTIC BALLOON (IAB) ACCESS CANNULA

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a medical device and the procedures for employing that device. More particularly, it relates to a cannula with multiple access ports for performing multiple simultaneous medical procedures. The present invention has particular utility in a combined procedure involving percutaneous cardiopulmonary bypass (PBY) augmented by intra-aortic balloon (IAB) counterpulsation. Of course, the cannula of the present invention may be used with equal advantage in many other procedures and combined procedures.

2. Description of the Prior Art

Percutaneous cardiopulmonary bypass (PBY) cannulae and procedures are known. For example, U.S. Pat. No. 4,804,365 (Litzie, et al.) relates to vascular cannulae for transfemoral cardiopulmonary bypass. When performing PBY, deoxygenated blood is removed through a first cannula inserted in a femoral vein of one of the patient's legs. The deoxygenated blood is fed to an external oxygenator and pump system, and then pumped back into the patient through a second cannula inserted in a femoral artery of one of the patient's legs. A number of practitioners and researchers in the field believe that one of the drawbacks of PBY is its tendency to increase back pressure in the aorta, thereby increasing the load on the heart muscle during systole.

Counterpulsation, also known as intra-aortic balloon pumping (IABP), using intra-aortic balloon (IAB) catheters is well known. For example, U.S. Pat. No. 4,261,339 (Hanson, et al.) describes an IAB catheter designed for counterpulsation therapy. Datascope Corp., the assignee of this Hanson et al. patent as well as of the present invention, markets several IAB catheters.

For percutaneous intra-aortic balloon counterpulsation, an IAB normally is inserted into the body through a femoral artery in the groin area of the patient. The IAB then is pushed up through the arterial tree until the balloon is located in the descending thoracic aorta. Inflation and deflation of the balloon causes a pumping action that supplements the natural pumping of the heart. Inflation of the balloon forces blood out of the aorta to other parts of the body. Deflation of the balloon creates a slightly lowered pressure in the aorta, which reduces the back-pressure against which the heart must work during the next pumping cycle.

Recently, research has suggested that counterpulsation, when employed concurrently with cardiopulmonary bypass may counteract, at least in part, the increased aortic pressure produced by PBY. (See, e.g., Bavaria, J.E., et al., "Effect of Circulatory Assist Devices on Stunned Myocardium," *Annals of Thoracic Surgery* 1990, 49:123-8; and Phillips, S.J., "Percutaneous Cardiopulmonary Bypass and Innovations in Clinical Counterpulsations," *Critical Care Clinics,* Vol. 2, No. 2, April 1986.)

Heretofore, PBY and IAB, if done by means of percutaneous insertions, have each required a separate puncture in the femoral artery. Such percutaneous puncture wound insertion sites are preferably located in the groin area of the patient's thigh where the femoral artery is closest to the surface of the skin and most easily accessible. However, access to the femoral artery in this area is limited and gaining access through two separate puncture wounds can be difficult. Two puncture wounds present other problems as well, including increased trauma, increased risk of infection and bleeding. Thus, it would be advantageous to be able to perform PBY and IABP simultaneously through a single percutaneous puncture wound.

It also is frequently the case that the physician is unable to determine in advance whether both procedures will be necessary or whether one or the other will suffice. It would, therefore, be advantageous for the physician to be able, for example, to initiate PBY and decide later whether to insert an IAB. A multi-port cannula according to the present invention provides that flexibility.

Y-shaped cannulae and cannula adapters for providing multiple access ports through a single insertion site are known. U.S. Pat. No. 4,287,892 (Schiff) describes such a device designed specifically for use with intra-aortic balloon (IAB) catheters. However, the device described in the Schiff patent is made solely for surgical procedure, not for percutaneous insertion. In addition, the cannula described in the Schiff patent must have an IAB catheter resident therein at all times.

In order to give the physician the flexibility of being able to decide, after insertion of the cannula, whether to use only one of the access ports or more than one, means must be provided to prevent bleeding through those access ports not in use. This can be accomplished by incorporating one or more hemostasis valves in the cannula structure.

Of course, it is known to use a hemostasis valve integral with an introducer sheath. Known hemostatic valves generally include passive self-closing valves, "open hole" valves and "active" valves.

A passive self-closing valve generally is a one-way valve designed to seal about a catheter or other intra-aortic device inserted therethrough, and to close upon itself when there is no device inserted therethrough. An example of a passive self-closing valve is a duck-bill valve. Such valves have particular utility in applications that require passive sealing of passages having a fluid pressure differential across the valve. However, a duck-bill valve generally permits insertion only from one direction, i.e., from the low pressure side. Also, the sizing of the duck-bill opening generally provides effective sealing for devices falling within a limited size range. If it is necessary to insert different devices having widely varying sizes, for example, a guide wire followed by an IAB catheter, the duck-bill valve may not be ideally suited for the task.

An open-hole valve is a two-way valve. Examples include O-ring inserts and perforated diaphragms. Such valves, however, generally provide effective sealing only when the insertion device is resident therein. Therefore, an obturator cap, heparin drip, heparin lock, or similar device is needed to prevent leaks when no catheter or other device is inserted therethrough.

An active valve may be a one-way or two-way valve that is opened or closed by manipulating the valve or one or more of its components. An example is a Touhy Borst valve. Such valves have particular utility where a user needs to provide a seal under changing conditions.

It is also known to use an introducer cannula having a hemostatic valve and a port arranged for introducing